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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,815	07/09/2001	Lars Lannfelt	LANNFELT1A	9645
466	7590	11/24/2004	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/899,815

Applicant(s)

LANNFELT ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,27,32,33 and 39-48 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 39-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,32,33 and 44-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of claims 27, 32-33 and 44-48 (Group II, as correctly identified in supplemental reply of September 21, 2004) in the reply filed on September 10, 2004 is acknowledged. The traversal is on the ground(s) that examination of both groups I and II would not impose a serious burden on the Examiner because "Invention I refers to active immunization of an inventive antibody [...] and Invention II refers to passive immunization of said inventive antibody" (bottom at page 6 of the Response). This is not found persuasive because, first, contrary to Applicant's statement that "[s]eparate classification is no evidence of the propriety of requirement for restriction" (bottom at page 7), MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed June 10, 2004. Furthermore, the Examiner has shown that the Groups I and II are independent or distinct for the reasons in the previous Office action (see Paper mailed on June 10, 2004) and, therefore, are capable to support separate patents (MPEP § 806.04 - § 806.04 (j) and MPEP § 806.05 - § 806.05 (i)). Finally, while it is true that the claims directed to administration of A β fragments were previously examined in a parent application, Applicant's argument regarding improper restriction requirement is not deemed persuasive because the issue at hand is not whether the groups achieve the same goal, i.e. treatment of Alzheimer's disease, but rather whether the method steps themselves require coextensive searches. In this case, the search for the method steps of Group II is quite distinct from that of the Group I, and would constitute a

Art Unit: 1646

burdensome search for the Examiner. A search is directed to references directed to art related to administration of a peptide and to administration of an antibody, to art, which would render the invention obvious, as well as references directed to anticipation of the invention, and, therefore, requires a search of relevant literature in many different areas of subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24 and 39-43 are withdrawn from further consideration pursuant to 37 CFR

1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 10, 2004.

Claims 27, 32-33 and 44-48 are under examination in the instant office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 27, 32-33 and 44-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 27, 44 and 46-48 are vague and indefinite in so far as they employ the term "A β -Arc peptide" as a limitation. This term is appears to be novel, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of "A β -Arc peptide". Moreover, because the instant specification does not identify

Art Unit: 1646

that property or combination of properties which is unique to and, therefore, definitive of a "A β -Arc peptide", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

4. Claims 45 and 48 are vague and ambiguous for recitation of a "protofibril is in combination with a mutation". The metes and bounds of the recitation cannot be determined from the claims or the instant specification. Applicant is advised that the distinguishing property of the instant invention, which defines it against prior art, is using a very specific molecular embodiment, a mutated form of A β , A β -Arc peptide. Therefore, in order to clearly define the claimed subject matter, definition of "a protofibril" is critical, as a distinctive feature lacking from prior art. Appropriate clarification is required.

5. Claims 27 and 44 are further vague and ambiguous for reciting "a therapeutically effective antibody". The metes and bounds of recitation cannot be determined from the claim or the instant specification. Applicant is advised that using recitation "a therapeutically effective amount of an antibody", for example, would obviate this ground of rejection.

6. Claim 32 is indefinite for being dependent from indefinite claim.

Double Patenting

7. Applicant is advised that should claim 27 be found allowable, claim 46 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other

Art Unit: 1646

as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, “Aβ-Arc peptide”, according to the instant specification (page 6, second paragraph of the instant specification), is an Aβ peptide with a specific mutation at position 22, such as recited in claim 46, which indicates that claim 46 is of the same scope as claim 27.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant’s representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Art Unit: 1646

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

November 22, 2004